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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/732,091 | 12/07/2000 | Jing-Hui Tian | 7969-088-999 | 3097 |

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| EXAMINER | |
|---|---|
| PORTNER, VIRGINIA ALLEN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |

DATE MAILED: 04/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/732,091 | TIAN ET AL. | |
| | Examiner | Art Unit | |
| | Ginny Portner | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *79-88* is/are pending in the application.

4a) Of the above claim(s) *80-82 and 87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79-80,82-86,88* is/are rejected.

7)☒ Claim(s) *79,80,82-86 and 88* is/are objected to.

8)☒ Claim(s) *79-88* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/04;1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-78 have been canceled.
All new claims have been submitted, claims 79-88.
Claims 81 (fragments) and 87(combination compositions not previously examined on the record) stand withdrawn from consideration; claim 80 (third species recited) and 82(c ) recite non-elected species directed to fragments of SEQ ID NO 4 (a non-elected invention).
1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Election/Restrictions*

2. Newly submitted claims **80** (third species recited directed to "a sequence greater than 80% identical to SEQ Id NO 4, and specifically binds an antibody that specifically binds to a polypeptide having the sequence of SEQ ID NO 4", which reads on a peptide fragment epitope based upon antibody binding as the claimed third species and is not directed to the previously examined HP30 polypeptide), **81, 82** subparagraph C); **87** (combination compositions directed to species not examined in the first action dated October 2, 2003) are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: An epitope based composition of at least 6 or 8 amino acids differs both structurally and functionally from a whole polypeptide comprising over 250 amino acids in length (SEQ ID No 4 is 253 amino acids in length) which comprises multiple epitopes.

3. Applicant in the paper dated April 2, 2004 elected the species directed to a 30 Kda polypeptide encoded by a nucleic acid of SEQ ID NO 3 and evidences an amino acid sequence of SEQ ID NO 4. A first action on the merits was set forth in the Office Action dated July 16, 2004 Tomb et al anticipating the elected invention. No additional species were required to be searched. All claims directed to non-elected species in paper dated April 2, 2004 are herein withdrawn from consideration.

4. Applicant's Representative traverses the Election/Restriction/Species Election set forth and made Final in a prior Office Action and requests rejoinder of the 30 kDa polypeptide with immunogenic fragments of the 30 kDa polypeptide. Applicant states that the epitopic fragments of full length HP30 polypeptides are obvious in light of the Applicant's disclosure.

5. It is the position of the Examiner that Applicant elected to prosecute Group I, species directed to a 30 kDa polypeptide and the Examiner applied prior art that anticipated the elected species (Tomb et al), no additional species were required to be searched.

6. With respect to Applicant's statement that epitopes of the full length HP30 polypeptide are obvious in light of Applicant's disclosure is not a statement that an epitope fragment is Not Patentably distinct from the whole protein/polypeptide HP30. Applicant has not submitted evidence or identified such evidence showing the species directed to immunogenic fragments of 6 amino acids are obvious variants or clearly admit on the record that this is the case. If evidence or admission is submitted, it may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. An obvious variant is not the same as an obviousness statement in light of guidance, suggestion and teaching which would lead one to obtain a product. An epitope based composition of 6 amino acids differs both structurally and functionally from a whole polypeptide comprising over 250 amino acids in length (SEQ ID No 4 is 253 amino acids in length) which comprises multiple epitopes. No evidence has been made of record showing that a single epitope (6-8 amino acids) containing fragment has the same or equivalent immunological or immunogenicity as a polypeptide that comprises a plurality of epitopes (253 amino acids) would

induce an immune response to a plurality of antigenic epitopes rather than a single antibody directed a single epitope containing fragment.

8. The election of species *was* made Final and is still Final; a first action on the merits has been made of record and anticipatory prior art applied against the elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 80 (fragment species)(a sequence 80% identical to SEQ ID NO 4; ie SEQ ID NO 4:----------(253 aa) ; claimed sequence only 10 aa: xx---------- (x being a non-identical residue, 2 different aa)and(8-------- identical amino acids); 81 (fragments),82 (subparagraph C, reads on fragments), claim 87 (not previously examined combination compositions withdrawn from consideration as being directed to a non-examined, non-elected species of invention). See 37 CFR 1.142(b) and MPEP § 821.03.

***Correspondence Table***

| **Original Claim** | **New Claim** |
|---|---|
| Claim 1 and 4 | Instant claim 79 |
| Claims 2-3 | Instant claim 83 |
| Claim 2 | Instant claim 84 |
| Claim 5 | Instant claim 80 (first or second recited species HP30) |
| Claim 41 | Instant claim 85 (generic recitation of reagents recited in claim 41) |
| Claim 41 | Instant claim 88 |

| | |
|---|---|
| Claims 1, 57-59 | Instant claim 82 (paragraphs A) and B)) |
| Claim 69 | Instant claim 86 |

**Ochiai/Brouwer Rejoinder**

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP ∋ 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See AGuidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. ∋ 103(b),≅ 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP ∋ 804.01.

***Rejections Withdrawn***

9. All prior claims have been canceled, but the references applied against claims 1-78 will be applied to newly submitted claims 79-80 and 82-86,88 in so far as the references apply to the elected invention recited in the newly submitted claims.

***Response to Arguments***

10. Applicant's representative admits on the record that Tomb et al disclose a polypeptide that shares 100% identity with SEQ ID NO 4, and that WO96' describes a polypeptide that shares 97% identity with SEQ Id NO 4 and that the polypeptides were recombinantly expressed.

11. It is the position of the examiner that compositions that comprise a Helicobacter polypeptide of SEQ ID NO 4, were known in the art, therefore Tomb et al inherently anticipate Applicant's invention despite the fact that the functional characteristics of the polypeptides were not known; compositions that comprised the polypeptides were described. See In re Atlas cited below.

***New Claims/New Claim Limitations/New Grounds of Objection/Rejection***

***Claim Objections***

12. New Claims 79-80,82-86 and 88 are objected to because of the following informalities: Claims 79-80,82-86,88 recite non-elected inventions.

13. Claims 83-86 and 88 depend from claim 81, which has been withdrawn from consideration as being directed to a non-elected invention and is therefore not further limiting of claim 81 from which they depend. Additionally, claims 83-88 depend from claims 79-80, and 82 which recite species of invention that are not under examination, and therefore encompass embodiments that are not under examination. Claims which depend from withdrawn claims and embodiments drawn to non-elected inventions are not clear as they depend from claims and embodiments that stand withdrawn from consideration. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

14. The term "effective amount" in claims is not defined for what it is effective for, and is a relative term which renders the claim indefinite. The term "effective amount" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and

one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. No specific amount is recited in the claims, because what the amount is functionally defined as being effective, but what it is effective for, is not claimed.

***Please Note:*** All claims which recite the term "vaccine" are being read as composition claims that comprise the recited components, the intended use being one of a vaccine.

***Claim Rejections - 35 USC § 102***

15. New Claims 79,80, 82,83,84,86 are rejected under 35 U.S.C. 102(b) as being anticipate by Tomb et al (August 9, 1997).

16. Tomb et al disclose the instantly claimed invention directed to:

**Instant claim 79-80**: a composition that comprises a Helicobacter polypeptide encoded by SEQ Id NO 3, and has the amino acid sequence of SEQ Id NO 4. Tomb et al referred to the polypeptide be a different designator, specifically HP1588 (see Tomb et al Table 2, col. 3, middle of column), and was encoded by a nucleic acid of EMBL accession number D64718 which comprises the nucleic acid for SEQ ID NO 3.

**Instant claim 82:** The claimed polypeptide composition is claimed as a product by process recombinantly produced HP30 polypeptide. Tomb et al recombinantly expressed the polypeptide that shares 100% sequence identity with SEQ ID NO 4, and named the polypeptide HP1588. Though the name is not HP30, it is the identical polypeptide to HP30 as it has the amino acid sequence of SEQ Id NO 4.

**Instant claim 83**: wherein the species is Helicobacter pylori (see title of reference).

**Instant claim 84:** wherein the species is Helicobacter felis. While Tomb et al does not discuss Helicobacter felis, the polypeptide of Tomb et al has the amino acid sequence of SEQ ID NO 4, and therefore anticipates the instantly claimed H.felis composition that is SEQ ID NO 4 which is set forth in claims 79-80 and 82, from which claim 84 depends.

**Instant claim 86**: further comprising one or more immunogens (Tomb et al expressed the H.pylori HP30 polypeptide is an E.coli laboratory strain of bacteria, see transcription and translation page 541, col. 1, paragraphs 2, which inherently comprises lipids, lipoproteins, proteins of E.coli, and the E.coli laboratory strain is a type of attenuated organism).

1. Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

***Claim Rejections - 35 USC § 103***

16. Claims 85 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomb et al as applied to claims 79-80, 82-84, and 86 above, in view of WO96/40893 (1996).

17. See discussion of Tomb et al above. Tomb et al describes an composition that comprises an HP30 polypeptide which has the amino acid sequence of SEQ Id NO 4, the polypeptide having been recombinantly expressed, the composition comprising one or more additionally immunogens associated with the host cell E.coli, but differs from the instantly claimed invention

by failing to show the polypeptide together with a pharmaceutically acceptable carrier and one or more adjuvants.

WO96/40893 show a polypeptide that shares identity with SEQ Id NO 4 (WO96 refers to the polypeptide as accession umber AAW20486) and is encoded by a sequence of SEQ ID NO 3, and teaches compositions that comprise Helicobacter polypeptides together with a pharmaceutically acceptable carrier and an adjuvant (see page 84, paragraphs 4-5 and page 85, paragraphs 1-4) in an analogous art for the purpose of formulating compositions that would induced an immune response (see page 85 last line) to H.pylori polypeptides; H.pylori being a known human pathogen associated with gastric ulcer disease and gastric adenocarcinoma (see page 1, lines 5-17 ).

It would have been obvious to the person of ordinary skill at the time the invention was made to modify the composition of Tomb et al with the carrier and adjuvant of WO96' because both references are directed to polypeptide compositions of H.pylori that comprise an amino acid sequence of SEQ ID NO 4, and WO96' suggests, teaches and provides guidance for the formulation of polypeptide containing compositions that further comprise a pharmaceutically acceptable carrier and an adjuvant (see WO96' pages 84-85) because WO96' teaches the importance of inducing an immune response to a known human pathogen known to be associated with severe disease, wherein induction of an immune response to the compositions results in the attainment of an antibody reagent for diagnostic and therapeutic purposes (see page 2, lines 18-19 and page 85, lines 37-39 and first paragraph on page 86).

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining compositions

that comprise a polypeptide, carrier and adjuvant because W096 teaches compositions that comprise Helicobacter polypeptides together with a pharmaceutically acceptable carrier and an adjuvant (see page 84, lines 26-34) and Tomb et al and WO96' are both directed to the formulation of compositions that will serve in inducing an immune response which can serve as a tool for gaining greater insight into the pathogenesis of H.pylori (see WO96', page 83, paragraphs 2-4), as well as vaccine development (see Tomb et al, page 539, col. 1, last line; see WO96' abstract) and WO96' teaches through incorporating the Helicobacter polypeptide in an effective amount (see WO96', page 84, last paragraph, first line) into a composition that comprises both a carrier to protect the antigen (see WO96' page 85, lines 32-33) from acidic environments and an adjuvant to obtain an enhanced immune response to the polypeptide, an immunogenic composition can be readily obtained.

Tomb et al in view of WO96' (alignment provided herewith) obviates the instantly claimed invention.

***Conclusion***

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bolin et al (US Pat. 6,025,162) is cited to show an antibody that is immunoreactive with a 30 kDa Helicobacter pylori antigen.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp April 12, 2005

LYNETTE R. F. SMITH
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